UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/862,442	05/23/97	SHYJAN	

EXAMINER

HM12/0521

J PETER FASSE
FISH & RICHARDSON
225 FRANKLIN STREET
BOSTON MA 02110-2804

ART UNIT	PAPER NUMBER
WORRALL, I	13

DATE MAILED: 05/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on March 1, 1999.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 29, 31-43, and 45-56 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 29, 34-43, and 45-56 is/are rejected.
☒ Claim(s) 31-33 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Applicant's amendment, filed March 11, 1999 (Paper No. 10), is acknowledged.

Claims 29, 39-43, and 45-50 have been amended.

Claim 51-56 has been added.

Claims 30 and 44 have been canceled.

Claims 29, 31-43, and 45-56 are pending.

Previous Rejections

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the parent application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for some claims of this application.

This application is a Divisional application of Application No. 08/623,679 filed April 16, 1996, which is a CIP of Application No. 08/412,431 (US Pat No: 5,412,431) filed March 29, 1995, and names the same inventor as the prior applications. The invention is drawn to a series of polypeptides encoded by polynucleotide sequences. Claims drawn to the polynucleotide sequence defined by SEQ ID NO:2 and the polypeptide sequence defined by SEQ ID NO:3 are enabled by Application 08/412,431 and have a priority date of March 29, 1995. As pointed out in the previous action and reiterated here, claims drawn to the specific sequences not included by SEQ ID NO:2 or 3 are not supported by other sequences are not enabled by the prior applications, and therefore have the April 16, 1996 priority date of Application 08/623,679.

Applicant has failed to provide evidence that the *specific* other claimed sequences in the application are supported in either prior application 08/623,679 or 08/412,431. Therefore, the claims 31, 37, 40, and 45 have the March 29, 1995, priority date, and claims 29, 30, 32-36, 38, 39, 41-44, and 46-50 have the April 16, 1996, priority date.

3. Based on Applicant's amendments of March 11, 1999 (Paper No. 10), the rejections under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 112 first paragraph are withdrawn.

4. The rejections under 35 U.S.C. 103 are withdrawn.

New Grounds for Rejection

Deposit

5. Claims 29, 34-36, and 54-56 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of the cDNA of the clone contained in ATCC Accession Nos. 97880 and 97881, and in NRRL Deposit NO. B-21416. It is not clear that clones possessing the identical properties of ATCC Accession Nos. 97880 and 97881, and NRRL Deposit NO. B-21416 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed cDNA, a suitable deposit of the cDNA for patent purposes, evidence of public availability of the claimed cDNA, or evidence of the reproducibility without undue experimentation of the claimed cDNA, is required.

Applicant's referral to the deposit of the cDNA as B-21416 on page 129 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposits are made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposits will be

replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the complete name and *address* of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If deposits are made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell lines described in the specification as filed are the same as those deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

New Matter

6. Claims 29, 37-39, 43, and 45 -50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The claims are drawn to a polypeptide comprising 15 amino acids of SEQ ID NOS: 3, 7, or 9. These claims were made in a preliminary amendment after the application was filed, and accordingly must be supported by the specification. The specification does not support claims to 15 amino acid fragments. Applicant is invited to point out where in the specification claims to 15 contiguous amino acids are found and supported.

Claim Rejections - 35 USC § 103

7. Claims 40, 51 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 5,487,985 ('985) in view of Zubay (Biochemistry, page 912, Adison-Wesley Publishing Company Inc. 1984). The claims are drawn to polypeptides encoded by a nucleic acid molecule that hybridizes to SEQ ID NO:2 at 68 degrees Celcius in 0.1X SSC, 0.1% SDS, and polypeptides encoded by at least 20 bases of nucleic acid sequences that hybridize under at 42 degrees Celcius in 0.2XSSC, 0.1% SDS to SEQ ID NO:2, or the cDNA clones contained in NRRL Deposit No. B-21426, ATTC Accession No. 97880, or ATTC Accession No. 97881.

'985 teaches a 26 base long sequence (SEQ ID NO:10) that would hybridize to the claimed sequences at the specified conditions. Given their broadest possible scope, the claims are drawn to cases in which even a small amount of the sequence would hybridize. SEQ ID NO: 10 of '985 would hybridize to the claimed sequence in smaller amounts under the claimed

hybridization conditions, but nevertheless would hybridize. Please see the attached sequence comparison. The reference differs from the instant invention by not teaching that a polypeptide is encoded by the sequence.

Zubay et al teach that polypeptides are produced by encoded polynucleotide sequences.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain a polypeptide encoded by at least 20 bases of nucleic acid sequences that hybridize under the given conditions, by expressing the DNA sequence defined in the '985 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to produce the polypeptide encoded by specific nucleic acid sequences within the library since it is well known in the art that polypeptide sequences are encoded by nucleic acid sequences. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claims 41, 42, and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 5,565,340 ('340) in view of Zubay (Biochemistry, page 912, Adison-Wesley Publishing Company Inc. 1984). The claims are drawn polypeptides encoded by at least 20 bases of nucleic acid sequences that hybridize under at 42 degrees Celcius in 0.2XSSC, 0.1% SDS to SEQ ID NOS:6 or 8, or the cDNA clones contained in NRRL Deposit No. B-21426, ATTC Accession No. 97880, or ATTC Accession No. 97881.

'340 teaches a 44 base long sequence (SEQ ID NO:5) that would hybridize to the claimed sequences at the specified conditions. Please see the attached sequence comparison. Given their broadest possible scope, the claims are drawn to cases in which even a small amount of the sequence would hybridize. SEQ ID NO: 5 of '340 would hybridize to the claimed sequence in

smaller amounts under the claimed hybridization conditions, but nevertheless would hybridize. The reference differs from the instant invention by not teaching that a polypeptide is encoded by the sequence.

Zubay et al teach that polypeptides are produced by encoded polynucleotide sequences.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain a polypeptide encoded by at least 20 bases of nucleic acid sequences that hybridize under the given conditions, by expressing the DNA sequence defined in the '340 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to produce the polypeptide encoded by specific nucleic acid sequences within the library since it is well known in the art that polypeptide sequences are encoded by nucleic acid sequences. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Objections

9. Claims 31, 32, and 33 are objected to as depending from a rejected claim.

Conclusion

10. NO CLAIM IS ALLOWED.

11. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Timothy A. Worrall, Ph.D. whose telephone number is (703) 308-9348. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014.

Communications via Internet-e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that

sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements under 35 U.S.C.122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997, at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Timothy A. Worrall, Ph.D.

May 19, 1999

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER